### Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 1 of 17

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

THUONG VAN TRAN, et al.,

NO. CIV. S-05-767 LKK/PAN

Plaintiffs,

v. <u>ORDER</u>

ORANGE COUNTY HEALTH AUTHORITY, et al.,

Defendants.

Plaintiffs, beneficiaries of the Medi-Cal Program and a group of pharmacists and pharmacies, seek to enjoin a pharmacy program established and administered by CalOptima, Orange County's Medi-Cal managed care plan. Plaintiffs bring suit against the Orange County Health Authority and members of its board of directors ("Orange County"), Sandra Shewry, the Director of the California Department of Health Services ("Shewry"), and Michael Leavitt, Secretary of the United States Department of Health and Human Services ("Leavitt").

### Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 2 of 17

Plaintiffs contend that Orange County sets pharmacy rates which violate the federal statewideness, comparability of services, and freedom of choice requirements under the Medi-Cal statute (first, second, and fifth claim); that defendants' extension of various waivers under the Medicaid statute was void <u>ab initio</u> (third claim); that defendants have violated § 14087.5 of the California Welfare and Institutions Code (fourth claim); that pharmaceutical rates and drug utilization restrictions violate § 1915 of the Social Security Act (fifth claim); that the CalOptima pharmacy rates are void because they were set in violation of the Social Security Act (sixth claim); and that defendants violated plaintiffs' equal protection rights under the Fourteenth Amendment (seventh claim). Pending before the court is plaintiffs' motion for three preliminary injunctions and defendants' motions to dismiss.¹

I.
BACKGROUND

Plaintiffs bring a number of claims related to a waiver of various Medicaid requirements issued by the Secretary ("Secretary") of the United States Department of Health and Human Services ("DHHS") to the California Department of Health Services ("Cal DHS" or "the Department").

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Defendants Orange County, Shewry, and Leavitt each move to dismiss plaintiffs' complaint.

### A. MEDICAID STATUTORY AND REGULATORY FRAMEWORK

The Medicaid program was established in 1965 by Title XIX of the Social Security Act, codified at 42 U.S.C. § 1396-1396v ("Medicaid statute" or "the Act"). Medicaid is a cooperative federal-state program through which the federal government provides financial assistance to states so that they may furnish medical care to needy individuals.

The basic requirements governing state Medicaid plans are set out in § 1902(a) of the Act, 42 U.S.C. § 1396a, and in regulations promulgated by the Secretary. See 42 C.F.R. Part 430 et seq. State Medicaid plans must be approved by DHHS, Centers for Medicare and Medicaid Services ("CMS"). 42 U.S.C. § 1396(a). State Medicaid plans must meet the requirements set forth in § 1902 of the Act and implementing regulations, including benefits, cost sharing, utilization and reimbursement requirements. Id.

Section 1915(b) of the Act, 42 U.S.C. § 1396n(b), authorizes the Secretary to waive certain requirements of § 1902 "to the extent he finds it to be cost-effective and efficient and not inconsistent with purposes of [Title XIX]." Under 42 U.S.C. § 1396n(b), the Secretary is permitted to waive the statewideness (§ 1396a(a)(1)), comparability of services (§ 1396a(23)), and freedom of choice requirements (§ 1396a(23)(A)).

Once CMS receives an application for a § 1396n(b) waiver from a state's Medicaid agency, the state's program will be deemed approved unless it is acted upon within 90 days. 42 U.S.C. § 1396n(f)(2); 42 C.F.R. Part 430.25(f)(3). Within this time

# Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 4 of 17

frame, CMS can approve, disapprove, or stop the 90-day clock if additional information about the program is needed. <u>Id</u>. The waiver programs are approved for two-year periods and can be renewed on an ongoing basis if the state seeks renewal. 42 U.S.C. § 1396n(h); 42 C.F.R. Part 430.25(h)(2)(ii), 431.55(b)(3).

In the case at bar, the Secretary granted a waiver of these three specific Medicaid provisions for approximately two years. Upon Cal DHS' request, the Secretary granted several renewals of the waivers, thus extending their effective period. <a href="Id.">Id.</a>

#### B. THE CALOPTIMA MEDI-CAL PROGRAM

The Cal DHS administers Medi-Cal, through which California participates in the federal Medicaid program. 42 U.S.C. \$\\$ 1396a-1396v. Defendant Sandra Shewry ("Shewry") is DHS' Director. Under Medi-Cal, Cal DHS pays providers directly on a fee-for-service basis, for specific services provided to beneficiaries.

Orange County Health Authority, dba CalOptima ("CalOptima"), is a local public agency and one of five County Organized Health Systems in California. In 1993, CalOptima was organized under \$ 14087.54 of the California Welfare and Institutions Code and Orange County Ordinance No. 3896, as amended by Ordinance No. 00-8. The ordinance mandates that CalOptima shall create and implement a Medi-Cal program that incorporates managed care concepts. Ordinance \$ 4-11-2.

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#### II.

### THE SECOND AMENDED COMPLAINT

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### IND DECOND AMENDED COMPLAINT

Before the court is plaintiffs' second amended complaint. The allegations of that complaint are summarized below.

In October 1995, DHHS and CalOptima entered into a written contract to ensure the provision of and payment for primary care and other related managed care services under the Medi-Cal program. Compl. at 10, 13, 14. On October 1, 1999, the same parties entered into a successor contract wherein CalOptima agreed to continue to ensure the delivery of Medi-Cal services in Orange County. Through these contracts, DHHS arranged with CalOptima, as a payer, to exclusively arrange for and pay providers to furnish Medi-Cal services to Medi-Cal beneficiaries residing in Orange County from federal-state funding, for the period of each contract. Compl. at 13. The contract has been amended from time to time and on July 5, 2005, the contract was further amended to extend through June 30, 2007.

The contract between DHHS and CalOptima contains provisions by which Cal DHS supervises and retains control of CalOptima with respect to (1) eligibility of beneficiaries and providers, (2) CalOptima provider rates, operational policies, and the amount, duration, and scope of pharmacy benefits to be furnished (none of which are authorized by the contract to be set or changed without Department written approval), and (3) to the processes by which CalOptima identifies and investigate fraud or by which to assess the potential of a pharmacy for fraud.

Under California law, the DHHS-CalOptima contract is contingent upon a valid federal waiver being issued by the Secretary of DHHS, without which the contract is prohibited from being implemented. Cal. Welf. & Inst. Code § 14807.5. On or before October 1, 1995, the Secretary of DHHS granted waivers of the following requirements of the Medicaid Act: (1) statewideness (§ 1396a(a)(1)); (2) comparability (§ 1396a(a)(10)(B)); freedom of choice requirement (§ 1396a9a)(23)(A)).

The waivers have been extended several times by the Secretary, with the most recent extension having been granted by letters sent by the Centers for Medicare and Medicaid Services, which were datestamped April 8, 2003, November 10, 2004, and July 5, 2005. Compl. at 15. The extension of the waiver by the most recent extension is for the period July 1, 2005 through July 30, 2007.

Plaintiffs contend that CalOptima has arranged for licensed pharmacies to furnish Medi-Cal services in the CalOptima program, claiming authority to do so under the DHHS-CalOptima contract. Compl. at 16. Plaintiffs maintain that at all times, pharmacy services have been and are arranged and paid for on a fee-for-services payment basis in the CalOptima pharmacy program, just as pharmacy services were performed on a fee-for-service basis by Orange County pharmacies in the statewide Medi-Cal pharmacy program. Id.

Plaintiffs allege that, since October 1, 1995, CalOptima and its governing board have engaged "in a series of acts under color of state law (namely, §§ 14087.5, 14087.54 WI Code)," which

### Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 7 of 17

"unlawfully circumvent and violate the statewideness requirement of § 1396a(a)(1), the comparability requirement of § 1396a(a)(23)(A)." The CEO of CalOptima, Richard Chambers, and his predecessors, "with knowledge of the facts, have also acted under the same color of state law to aid and abet the implementation of these violations of the Medicaid Act." Compl. at 16.

At all times since October 1995, DHHS allegedly allowed CalOptima to set, and CalOptima has set, pharmacy rates, including the current CalOptima pharmacy rates, each of which has violated and currently violates the statewideness requirement. Plaintiffs contend that the rates set were different and substantially less than the rates which are paid to pharmacies in the statewide program. Since October 1995, DHHS has allowed CalOptima to set drug utilization restrictions, many of which violate the statewide and comparability requirements. Compl. at 17. The drug utilization rules allegedly reduce the services in the CalOptima pharmacy program to substantially less than the amount, duration, and scope of pharmacy services which are provided to beneficiaries in the statewide Medi-Cal fee-for-service pharmacy program. Id.

At all times DHHS allowed CalOptima to adopt a regulation, CalOptima Policy GG. 1406 ("CalOptima pharmacy eligibility policy"), which restricts beneficiaries in the CalOptima program from:

a. using any pharmacy which has not been accepted by a specified entity into its private pharmacy network

- b. using any pharmacy which has not been certified by a specified unlicensed unregulated private "fraud assessment organization" ("FAO")
- c. using any new pharmacy in Orange County which is not owned by a pharmacy already accepted by the private entity network.

DHHS has never requested and has never received approval of any request for any waiver of these requirements with respect to the CalOptima pharmacy program. Compl. at 18-19

Plaintiffs also allege that the application for the § 1915 waiver and its extensions failed to specify or show what restrictions of choice of pharmacy providers were to be made or allowed under the (b) (4) waiver. Compl. at 23. Plaintiffs contend that the actions of the Secretary to grant the § 1915 waiver, and to extend the waiver through June 30, 2007, were void because the Secretary had no valid basis on which to grant the requested waiver. Id.

It is further alleged that the Secretary knew that there had been virtually 100% participation by Orange County pharmacies in the statewide Medi-Cal fee-for-services program. It is alleged that it has never been necessary to restrict the pharmacies in Orange County from whom a beneficiary may receive pharmacy services, in order to enable beneficiaries to obtain pharmacy services effectively and efficiently. Compl. at 24. The Secretary's decision to grant and extend the Section 1915 waiver with respect to the CalOptima pharmacy program was arbitrary, capricious, and contrary to law. Compl. at 24.

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# Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 9 of 17

By virtue of the waiver, CalOptima adopted pharmacy rates which are different from the statewide Medi-Cal fee-for-services pharmacy program, and adopted drug utilization restrictions which reduced the amount, duration and scope of pharmacy services violating the statewideness and comparability requirements of (a) (1) and (b) (4) of Social Security Act § 1915.

The pharmacy rates set by CalOptima since October 1, 1995 have been set without regard for and in violation of the procedural requirements imposed upon CalOptima both by § 30A and by Subd. (b) (4) in that the governing board of CalOptima failed to consider the relevant factors, the costs to pharmacies, failed to consider the costs to pharmacies to acquire and furnish prescribed drugs, failed to obtain or use any factual study to justify its restrictions, failed to consider the factor of reasonable profit for those furnishing quality services, and in setting each of the rates, budgetary considerations were the conclusive factor in the determination of the rate by the board. Compl. 29-30.

As a result of all the above, the beneficiary plaintiffs, and the pharmacy plaintiffs in their individual capacity, and as representatives of their beneficiary patients, each suffered and will continue to suffer irreparable injury. Compl. at 30-31.

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III.

STANDARDS

## A. DISMISSAL STANDARDS UNDER FED. R. CIV. P. 12(b)(6)

On a motion to dismiss, the allegations of the complaint must be accepted as true. See Cruz v. Beto, 405 U.S. 319, 322 (1972). The court is bound to give the plaintiff the benefit of every reasonable inference to be drawn from the "well-pleaded" allegations of the complaint. See Retail Clerks Intern. Ass'n, Local 1625, AFL-CIO v. Schermerhorn, 373 U.S. 746, 753 n.6 (1963). Thus, the plaintiff need not necessarily plead a particular fact if that fact is a reasonable inference from facts properly alleged. See id.; see also Wheeldin v. Wheeler, 373 U.S. 647, 648 (1963) (inferring fact from allegations of complaint).

In general, the complaint is construed favorably to the pleader. See Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). So construed, the court may not dismiss the complaint for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim which would entitle him or her to relief. See Hishon v. King & Spalding, 467 U.S. 69, 73 (1984) (citing Conley v. Gibson, 355 U.S. 41, 45-46 (1957)). In spite of the deference the court is bound to pay to the plaintiff's allegations, however, it is not proper for the court to assume that "the [plaintiff] can prove facts which [he or she] has not alleged, or that the defendants have violated the . . . laws in ways that have not been alleged." Associated General Contractors of California, Inc. v. California State Council of

<u>Carpenters</u>, 459 U.S. 519, 526 (1983).

### B. STANDARD FOR A PRELIMINARY INJUNCTION

The Ninth Circuit's longstanding standard for a preliminary injunction is well known: The moving party must show either (1) a combination of probable success on the merits and the possibility of irreparable injury, or (2) that serious questions are raised and the balance of hardships tips sharply in favor of the moving party.

Dr. Seuss Enters. v. Penguin Books USA, Inc., 109 F.3d 1394, 1397 n. 1 (9th Cir. 1997). These standards "are not separate tests but the outer reaches of a single continuum." International Jensen, Inc. v. Metrosound U.S.A., 4 F.3d 819, 822 (9th Cir. 1993) (citation omitted).

The court in any situation must find that there is at least a fair chance of success on the merits, see Johnnson v. California State Bd. of Accountancy, 72 F.3d 1427, 1430 (9th Cir. 1995), and that there is some threat of an immediate irreparable injury. See Big County Foods, Inc. v. Board of Ed. of the Anchorage School Dist., 868 F.2d 1085, 1088 (9th Cir. 1989). Furthermore, "[t]he issuance of an ex parte temporary restraining order is an emergency procedure, and is appropriate only when the applicant is in need of immediate relief." Wright, Miller & Kane, Federal Practice and Procedure: Civil 2d § 2951 at 256-57 (footnote omitted).

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ANALYSIS

\_\_\_\_This matter is before the court on plaintiffs' motion for three preliminary injunctions and on defendants' motions to dismiss.

As the court understands plaintiffs' complaint, their central contention is that the federal defendant has, by virtue of the \$ 1915 waiver, wrongfully permitted the state and local agency defendants to set pharmacy rates and drug utilization rates which violate requirements of statewideness, comparability of services, and freedom of choice provisions which would otherwise apply under the Medicaid statute, and that by virtue of the waiver the state and local defendants are violating Cal. Welf. & Inst. Code \$ 14097.5, and that the plaintiffs have been deprived of the equal protection guaranteed by the federal Constitution.

The statutory and regulatory regime at issue is fairly complex, and unfortunately, plaintiffs' briefs are convoluted and sometimes self-contradictory. Nonetheless, it appears that many of the substantive issues raised should not be addressed by the court because plaintiffs' present pleadings seek redress under a statute which is not applicable to their claims. For that reason, the court concludes that plaintiffs' motion for preliminary injunctions must be denied, and defendants' motions to dismiss must be granted.

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#### B. SUIT UNDER 42 U.S.C. § 1983

Plaintiffs assert that they sue under 42 U.S.C. § 1983, and disavow any claim under the Administrative Procedure Act.

Plaintiffs' claims, however, demonstrate that suit under § 1983 does not lie for most of the causes of action. Plaintiffs' central claim is that the Secretary was not authorized to approve federal waivers, where "there is no claim or showing . . . that the restriction in choice of approval . . . will result in reducing the state's costs or the rate of increase in the state's cost." Compl. at 18. Elsewhere, plaintiffs maintain that the waiver application "must show facts to sustain or authorize the waiver, extension, or license to be approved." Compl. at 11. In sum, the allegation is that the waivers were unlawful and thus CalOptima's conduct violates the MediCare statute. Such allegations, by their very nature, challenge agency action and thus fall within the purview of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706.2

<sup>&</sup>lt;sup>2</sup> The statute provides that:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

<sup>(1)</sup> compel agency action unlawfully withheld or unreasonably delayed; and

<sup>(2)</sup> hold unlawful and set aside agency action, findings, and conclusions found to be--

<sup>(</sup>A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

<sup>(</sup>B) contrary to constitutional right, power, privilege, or immunity;

<sup>(</sup>C) in excess of statutory jurisdiction, authority, or limitations, or short of

# Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 14 of 17

Nonetheless, as noted, plaintiffs insist that "this [action] is not
. . . an APA proceeding." Pl.'s Repl. at 20.3 Plaintiffs'
insistence is without effect. It is well-established that a suit
under § 1983 does not lie where Congress has provided a specific
remedy for the challenged conduct. Middlesex County Sewerage
Authority v. National Sea Clammers Ass'n, 453 U.S. 1, 20 (1981)
("When the remedial devices provided in a particular Act are
sufficiently comprehensive, they may suffice to demonstrate
congressional intent to preclude the remedy of suits under
§ 1983"); see also Almond Hill Sch. v. U.S. Dep't of Agric., 768
F.2d 1030, 1035-36 (9th Cir.1985); cf. Jett v. Dallas Indep. Sch.
Dist., 491 U.S. 701 (1989).4 To put it somewhat differently,
plaintiffs cannot forego the remedy Congress provided for
challenges to administrative determinations under the Medicaid
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statutory right;

5 U.S.C.A. § 706.

<sup>(</sup>D) without observance of procedure required by law;

<sup>(</sup>E) unsupported.

<sup>&</sup>lt;sup>3</sup> At oral argument, plaintiffs confirmed that they are not bringing suit under the APA, although counsel, perhaps anticipating the court's ruling, suggested that he might amend the complaint to include such a claim.

Plaintiffs also assert standing, and one assumes a cause of action, under the Supremacy Clause. The contention is without merit. It is firmly established that the Supremacy Clause does not create any independent federal rights. Golden State Transit Corp. v. City of Los Angeles, 493 U.S. 103, 107 (1989). Rather, the Supremacy Clause provides the basis for suit to a plaintiff with standing to strike down state law which conflicts with preempting federal law. Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 74 (1st Cir. 2001).

Statute in favor of a suit under the Civil Rights Act.<sup>5</sup> Thus, causes of action one through four, and six must be dismissed.

### C. CALIFORNIA WELFARE AND INSTITUTIONS CODE § 14087.5

Plaintiffs bring suit under § 14087.5 of the California Welfare and Institutions Code.<sup>6</sup> This cause of action does not directly challenge the Secretary's determination to grant a waiver, and thus is not subject to the analysis undertaken above.<sup>7</sup>

According to plaintiffs, this section prohibited the CalOptima contract from being implemented. Compl. at 26. Although plaintiffs bring suit under a provision of California law, it is clear that plaintiffs' claims are rooted in allegations that the state has not complied with federally-imposed conditions under the Medicaid statute. Such a suit does not lie in federal court. See Pennhurst State School & Hospital v. Halderman, 465 U.S. 89, 106 (1984). In Pennhurst, the Supreme Court taught that "the typical remedy for state noncompliance with federally-imposed

There are innumerable other problems with plaintiffs' claim under § 1983. See, e.g., Gonzaga University v. Doe, 536 U.S. 273, 283 (2002); see also Sanchez v. Johnson, 416 F.3d 1051 (9th Cir. 2005). Moreover, as defendant Leavitt notes, § 1983 is limited to violations of federal rights under color of state law. When issuing the waivers challenged here, the Secretary acted under color of federal law.

The statute provides that the "department shall seek all federal waivers necessary to allow for federal financial participation in expenditures under this article . . . and that "[t]his article shall not be implemented until all necessary waivers have been approved by the federal government."

 $<sup>^{7}\,</sup>$  Obviously, since the statute addresses the duty of state and local agencies, the federal defendants are not proper targets of this cause of action.

conditions is not a private cause of action for noncompliance
but rather action by the Federal Government to terminate funds
to the State." <u>Id</u>. at 28. Consequently, plaintiffs' claim, a
private right of action for the state's alleged noncompliance,
must fail, and the cause of action must be dismissed.

### D. EQUAL PROTECTION CLAIM

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Plaintiffs allege in their seventh claim that the difference in purported lower rates paid to pharmacies in the CalOptima program as compared to those in the statewide Medi-Cal program violates the Equal Protection Clause of the federal Constitution. As defendant Shewry notes, courts will "presume the constitutionality of the statutory discriminations and require only the classification challenged be rationally related to a legitimate state interest." City of New Orleans v. Dukes, 427 U.S. 297, 303 (1976). Defendants explain that MediCal rates and services may vary across the state "depending on differences in area demographics and services provided." Shewry Mot. at 20 (citing Clayworth, 295 F.Supp.2d at 1125 and Blagojevich, 324 F.3d 906 (9th Cir. 2003)). Of course, variances in treatment premised upon legally-cognizable differences, i.e., the fact that the classes are not similarly situated, do not offend the Equal Protection clause. If the classification has some "reasonable basis," it does not offend the Constitution simply because in "practice it results in some inequality." <u>Dandridge</u> v. Williams, 397 U.S. 471, 485(1970) (involving statute that provides Aid to Families With Dependent Children) (quotation

### Case 2:05-cv-00767-LKK-DAD Document 105 Filed 12/06/05 Page 17 of 17

omitted). See also McGown v. Maryland, 366 U.S. 420, 426 (1961) ("A statutory discrimination will not be set aside if any state of facts reasonably may be conceived to justify it"). Thus, in the matter at bar, CalOptima is a managed care program and operates entirely differently than a fee-for-service program. For the reasons stated in Shewry's motion, the court finds that the purported discriminatory effect is legally permissible and passes muster under rational basis review.

Accordingly, defendants' motions to dismiss are GRANTED.

Plaintiffs' motions for a preliminary injunction are DENIED.8

IT IS SO ORDERED.

DATED: December 6, 2005.

/s/Lawrence K. Karlton
LAWRENCE K. KARLTON
SENIOR JUDGE
UNITED STATES DISTRICT COURT

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During oral argument, the parties discussed with the court whether plaintiffs should be granted leave to amend their complaint. Plaintiffs intimated that they would amend their complaint to include a claim under the Administrative Procedure Defendants vehemently objected to the court granting leave to amend, noting that plaintiffs have already amended their complaint twice and that defendants have spent significant time and resources defending their actions in various law suits, including this one. Although the court recognizes defendants' frustration, because the court cannot conclude that amendment would be "futile" at this point and because of the generous standard under Fed. R. Civ. P. 15(a) (The Federal Rules provide that leave to amend pleadings "shall be freely given when justice so requires"), the court must grant plaintiffs twenty days from the date of this order to amend their complaint. Plaintiffs are admonished that the court will not look kindly upon any amendments which would be futile and will issue sanctions for frivolous amendments.